

NRC INSPECTION MANUAL

PIPB

PART 9900: TECHNICAL GUIDANCE

SAFETY.TG

OPERATIONS - SAFETY AND COMPLIANCE

A. PURPOSE

The Commission has approved the attached discussion of safety and compliance. This guidance is incorporated into the NRC Inspection Manual for use by all NRC staff.

B. SAFETY AND COMPLIANCE

As commonly understood, safety means freedom from exposure to danger, or protection from harm. In a practical sense, an activity is deemed to be safe if the perceived risks are judged to be acceptable. The Atomic Energy Act of 1954, as amended, establishes "adequate protection" as the standard of safety on which NRC regulation is based. In the context of NRC regulation, safety means avoiding undue risk or, stated another way, providing reasonable assurance of adequate protection for the public in connection with the use of source, byproduct and special nuclear materials.

The definition of compliance is much simpler. Compliance simply means meeting applicable regulatory requirements.

What is the nexus between compliance and safety?

1. Safety is the fundamental regulatory objective, and compliance with NRC requirements plays a fundamental role in giving the NRC confidence that safety is being maintained. NRC requirements, including technical specifications, other license conditions, orders, and regulations, have been designed to ensure adequate protection--which corresponds to "no undue risk to public health and safety"--through acceptable design, construction, operation, maintenance, modification, and quality assurance measures. In the context of risk-informed regulation, compliance plays a very important role in ensuring that key assumptions used in underlying risk and engineering analyses remain valid.
2. Adequate protection is presumptively assured by compliance with NRC requirements. Circumstances may arise, however, where new information reveals, for example, that an unforeseen hazard exists or that there is a substantially

greater potential for a known hazard to occur. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety.

3. The NRC has the authority to exercise discretion to permit continued operations--despite the existence of a noncompliance--where the noncompliance is not significant from a risk perspective and does not, in the particular circumstances, pose an undue risk to public health and safety. When non-compliances occur, the NRC must evaluate the degree of risk posed by that non-compliance to determine if specific immediate action is required. Where needed to ensure adequate protection of public health and safety, the NRC may demand immediate licensee action, up to and including a shutdown or cessation of licensed activities. In addition, in determining the appropriate action to be taken, the NRC must evaluate the non-compliance both in terms of its direct safety and regulatory significance and by assessing whether it is part of a pattern of non-compliance (i.e., the degree of pervasiveness) that can lead to the determination that licensee control processes are no longer adequate to ensure protection of the public health and safety. Based on the NRC's evaluation, the appropriate action could include refraining from taking any action, taking specific enforcement action, issuing orders, or providing input to other regulatory actions or assessments, such as increased oversight (e.g., increased inspection).
4. Where requirements exist that the NRC concludes have no safety benefit, the NRC can and should take action, as appropriate, to modify or remove such requirements from the regulations or licenses. Requirements that are duplicative, unnecessary, or unnecessarily burdensome can actually have a negative safety impact. They also can tend to create an inappropriate NRC and licensee focus on "safety versus compliance" debates. As the Commission states in its Principles of Good Regulation. "There should be a clear nexus between regulations and agency goals and objectives, whether explicitly or implicitly stated."
5. Since some requirements are more important to safety than others, the Commission should use a risk-informed approach wherever possible when adding, removing, or modifying NRC regulations, as well as when applying NRC resources to the oversight of licensed activities (this includes enforcement). Based on the accumulation of operating experience and the increasing sophistication of risk analysis, the NRC should continue to refine its regulatory approach in a manner that enhances and reaffirms our fundamental safety objective.

These principles attempt to describe the nexus between compliance and safety. The misperception that compliance and safety are somehow incompatible or unrelated arises when the principles just outlined are not understood or are wrongly applied. When understood and applied correctly, the result should be a consistent, credible regulatory approach--as applied to licensing, inspection, enforcement, performance assessment processes, and rulemaking.

END

